

Butler, Jennie C

From: Peter Vardon [PVardon@bangate.fda.gov]
Sent: Monday, August 02, 1999 9:08 AM
To: JBUTLER1@test.oc.fda.gov
Subject: Fwd: GMP's and Herbal References

----- Original Message -----

To: Peter Vardon@OSAS@FDA.CFSAN
From: <SALTSPRING@aol.com>
Date: Thu Jul 29 11:48:37 1999
Attached: None

Dear Mr. Vardon,

I am resending my past message with the corrected e-mail address. Sorry.

Dear Mr. Vardon,

Please accept my apology for taking so long to get back to you. Everything that I am doing right now is small scale which means that I work twice the hours at 1/2 the pay and end up doing a lot of running around. I really enjoyed meeting with you at the Flamingo Hilton in Las Vegas and am very anxious to share my knowledge and resources with you and the FDA in order to improve the quality and safety of the products that we offer to the public. I was also very encouraged by the friendly and cooperative tone of the FDA's approach to the issue of Nutritional GMP's. Your willingness to discuss the GMP issue as it relates to both large and small scale companies is very much appreciated. I can't imagine any serious and responsible company, regardless of the scale of their operations, debating the need for GMP's. The adoption of reasonable Nutritional GMP's will be of great benefit to our industry as long as they are designed to promote critical safety and quality standards in a manner that does not put responsible small companies out of business. I believe that this goal can be achieved and will do my best to provide you with suggestions that may assist you in your efforts. I will plan to forward my suggestions to you by the end of next week.

With regard to the quality references that we discussed, I would suggest the following:

Herbs of Commerce American Herbal Products Association

This spiral bound publication represents an ongoing attempt to harmonize herbal nomenclature. Common names (which are both numerous and somewhat variable) are cross referenced with Latin binomials. This publication is very useful and has apparently been recognized by the FDA. The last time that I checked, this publication was being revised and the updated version should be available shortly.

Botanical Safety Handbook American Herbal Products Association (CRC Press)

A limited but solid attempt to provide reliable safety data for a wide range of popular botanicals. Herbs are classified according to a simple safety scale with usage limitations and caution and warning statements included. I use this book extensively when I am formulating new products and when I am creating labels. Used in concert with Herbs of Commerce.

Commision E Monographs American Botanicals Council Translation

The first comprehensive and reliable translation of the German Commission E Herbal Monographs. A very important reference that has been presented in a updated form that even the Germans envy.

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These references are available from the American Herbal Products Association
Phone: (301) 588-1171 Fax: (301) 588-1174 e-mail: AHPA@ix.netcom.com

The Lawrence Review of Natural Products Facts and Comparisons

Simple herbal monographs updated monthly. Very valuable and fully referenced information. A very handy guidebook from the publishers of the Facts and Comparisons drug reference that is found in almost every pharmacy.

This reference is available from Facts and Comparisons, Division of J.B. Lippincott Company, St. Louis, Missouri Tel(314) 878-2515

There are many others and I will forward additional information to you ASAP.

Best Regards,

Edward M. Lieskovan, Pharm.D.